

REMARKS

Applicant respectfully requests entry of the above amendments under the provisions of 37 C.F.R. §1.116(b); reconsideration of this application in view of the foregoing amendments and in view of the reasons that follow; and allowance of all of the claims remaining therein.

Amendments

Claims 19-30 and 46-59 are now pending in this application.

Claims 24 and 51 are amended to place these claims into independent form.

Insofar as these amendments reduce issues on appeal in that they provide for clear delineation over the cited art, entry of these amendments under the provisions of 37 C.F.R. §1.116(b) is appropriate. Entry of these amendments is requested.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Examiner Interview

Applicant thanks the examiner for the courtesy extended to the undersigned, Gerald Swiss (Reg. No. 30,113) and Bill Chan (Assignee's representative) in the telephonic interviews of 5 October 2006 and 30 November 2006. The Examiner's Interview Summary accurately reflects the matters addressed in the interview of 5 October 2006. In the interview of 30 November 2006, the Rook et al. and Maeda et al. references were discussed. While no agreement was reached, the following discussion reiterates the points made by Applicant during the interview.

Rejection Under 35 U.S.C. §102(b)

Claims 19-23, 25-30, 46-50 and 52-59 stand rejected under 35 U.S.C. §102(b) over Rook, et al., J. Investig. Dermatol. Symp. Proc., 1999, Sept. 4(1):85-89 as evidenced by Maeda, et al., J. Immunol., 174(10):5968-5976 (2005). For the following reasons, this rejection is traversed.

Applicant submits claims 19, 46, 58 and 59, and their dependent claims, are not anticipated by Rook et al., as evidenced by Maeda. The Office Action asserts that

Rook et al., teach at the first line of the abstract teach (sic?)
“Photopheresis is a leukapheresis-based therapy that utilizes 8-methoxypsoralen and ultraviolet A irradiation. Photopheresis is currently available at approximately 150 medical centers worldwide.”
The cells used in “photopheresis” of Rook et al., and the limitation “apoptotic bodies” in the instant base claims 19, 46, 58, and 59 do not appear to have any material differences. Rather the difference is semantic as evidenced by Maeda et al., who teach that “Photopheresis” generates apoptotic cells (note the title, and page 5970, left column under the heading “8-MOP/UVA induce apoptosis”). (quotations in original).

Applicant submits that the Examiner has failed to meet the burden to establish a *prima facie* case of inherent anticipation. It is well settled that the burden of establishing a *prima facie* case of anticipation resides with the Patent and Trademark Office. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785,788 (Fed. Cir. 1984) quoting *in re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173, 177 (CCPA 1967). When the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705,708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). However before an applicant can be put to the burdensome task of proving that the subject matter of the prior art does not possess the characteristic relied upon by the PTO, the Examiner must provide some evidence or scientific reasoning to establish the reasonableness of the Examiner’s belief that the functional limitation is an inherent characteristic of the prior art. *Ex parte Skinner*, 2 USPQ2d 1788, 1789 (Bd. Pat. App. 1986). In this case the Examiner has failed to provide adequate evidence or scientific reasoning in support of her belief that Rook et al. discloses a method comprising administering an effective amount of apoptotic bodies to a patient let alone

for treatment and/or prophylaxis of inflammation in a mammalian patient, wherein such apoptotic bodies have particular characteristics, to up-regulate the *in vivo* generation of anti-inflammatory Th-2 derived cytokines and/or down regulate the *in vivo* generation of pro-inflammatory Th-1 derived cytokines thereby reducing the level of inflammation in the treated patient.

A review of the Maeda et al. reference, particularly at the portion cited by the Examiner (*i.e.* page 5970, left column), indicates that apoptosis of cells only develops over an extended period of time, measured in days (see section titled “8-MOP/UVA induces apoptosis” and Figure 2). The observation in Maeda et al. is entirely consistent with a study cited in the Rook et al. reference, which indicates that “the combination of 8-MOP and ultraviolet A irradiation causes the majority of treated T cells to undergo apoptosis within 48 h of the photopheresis procedure (Yoo *et al*, 1996).” Rook et al. at page 89, left column. Contrarily, Maeda et al. only disclose the administration of pre-apoptotic bodies to a patient¹, rather than administration of actual apoptotic bodies, as required by the present claims.

Although the referenced prior art provides data that appears to indicate that incubation of certain cells for several days after treatment with 8-MOP and ultraviolet A light may induce apoptosis, nothing in the Rook reference or the Maeda reference indicate that cells are withdrawn from the body, treated, and then incubated *extracorporeally for several days* until the cells become apoptotic.

Applicant submits that unless or until the Examiner provides evidence or scientific reasoning to support a conclusion that Rook et al. discloses the administration of apoptotic bodies, rather than pre-apoptotic bodies (that may or may not become apoptotic over the process of several days), the Examiner has not met the necessary burden to establish a *prima facie* case of inherent anticipation. Applicant requests withdrawal of the rejection under 35 U.S.C. § 102.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date 20 December 2006

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¹ See Maeda, et al. at page 5971, right column, lines 14-17 of the Discussion.